prosthetic blood vessels (intraluminal grafts) is throughout the specification as well as in these claims as originally filed, see, for example, page 8, lines 8-15, and page 5, line 30 to page 6, line 2.

II. APPLICANTS' INVENTION

The present invention relates to a polymeric tube which circumferentially distends from an initial circumference upon the application of a circumferentially distending force such as applied by an internal pressure, and which exhibits minimal recoil following the removal of the circumferentially distending force. The polymeric tube preferably has a second circumference larger than the initial circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. It is useful as a liner for pipes and vessels, particularly those having irregular luminal surfaces to which the polymeric tube can smoothly conform. The tube is most preferably made from porous PTFE, in which form it is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilitation of the blood vessel to which it is fitted.

III. REJECTION OF CLAIMS 14, 17, 19, 24, 25, 31, 45, 58, 74, 82, 87, 88, 95 and 96 UNDER 35 USC 112, SECOND PARAGRAPH AS BEING INDEFINITE.

The Examiner states that the claims which recite that the tube comprises a vascular graft or an intraluminal graft are not understood and that it is not clear if the tube is intended to have an additional graft layer or if the tube is intended to be the vascular graft or intraluminal graft itself. The latter is the actual case, no additional layer is specified by (for example) claim 24 which depends directly from claim 1. These claims have now been amended by replacing "comprises" or "comprising" with --adapted for use as--. Tubes of the present invention sold for use as vascular or intraluminal grafts will be provided in clean (probably sterile) form and with instructions for surgical use, as is common practice for vascular grafts and intraluminal grafts. Porous polymeric tubes of the present invention are thus adapted for use in these conventional manners for vascular or intraluminal graft applications. While the original form of the claims is believed to be definite for these reasons, the amendment encompasses the normal aspects of use of the product as either a vascular graft or more specifically an intraluminal graft for the same reasons and should resolve the rejection.

Regarding claims 17 and 31, the Examiner notes that "the second circumference" lacks antecedent basis. Applicants would point out that both of these claims depend from claim 1 which provides antecedent basis for "second circumference" in the third line of that claim.

IV. REJECTION OF CLAIMS 1-5, 24-30, 33-35, 42-49, 51-55, 57-61, 63-67 and 69-97 UNDER 35 USC 102(b) AS BEING ANTICIPATED BY LEE, US 5,123,917.

Lee describes an expandable intraluminal graft in the form of an expandable polymeric tubular graft in combination with a metallic stent. The Examiner points out that the expansion limit of the graft layer is reached due to the expansion of the stent which will permit only a predetermined expansion due to the stent configuration and structure. The claims have been amended to require that the tube of the present invention is a porous polymeric tube; because of the stent required by Lee which is not required to provide the expansion limit (second circumference) of the porous polymeric tube of the present invention, the claims as amended are not anticipated by Lee. Lee does not teach or suggest how the tubular graft might be made to provide the claimed attributes without the use of a stent.

The Examiner also notes that the device of Lee does not appear to have a recoil. This is not at all apparent from the specification of Lee. Assuming, arguendo, that the graft of Lee lacks recoil, the lack of recoil would have to be considered due to the presence of the metallic stent segments which would prevent recoil only in the regions of the tube where a stent is present, i.e., the regions of the tube not supported directly by the stent will recoil. Recoil has been a long-standing difficulty with porous PTFE tubes used as circumferentially distensible intraluminal grafts. According to the claims as amended to further differentiate from Lee, the reference does not anticipate the claims specifically pertaining to recoil.

V. REJECTION OF CLAIMS 1, 2, 5, 24-30, 33-35, 42-48, 51-54, 58-60, 63-66, 69, 70, 72, 74, 76, 78, 80, 82, 84 AND 86-97 UNDER 35 USC 102(b) AS BEING ANTICIPATED BY RHODES, US 5,122,154.

Rhodes describes a stent and tube combination which is very similar to that of Lee. It also requires a stent to provide a limit to circumferential distension. For the same reasons described above in Paragraph IV with regard to Lee, the amended claims are not anticipated by Rhodes.

VI. REJECTION OF CLAIMS 6-16, 19, 21-23 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER LEE ('917) IN VIEW OF EILENTROPP, US 4,791,966.

Lee is described above. Eilentropp teaches a tube of non-porous PTFE formed by a helical layer of wrapped non-porous PTFE tape. The tape has a trapezoidal cross section, thicker at the center of the tape than at the edges which allows for the tape edges to overlap during wrapping and still result in a tube of relatively uniform wall thickness. The Examiner states that it would have been obvious to have formed the outer layer of Lee of helically wrapped tape per Eilentropp because the helically layered tube would have been merely an alternate and analogous method of forming another layer on the Lee device.

The present invention differs from Lee as noted above in that it does not require a stent to limit the circumferential distension. As noted above, Lee neither teaches or suggests the present

invention according to the amended claims. The addition of Eilentropp renders the present claims (and specifically the claims of the present rejection) even less obvious as follows. The background of the present specification at page 2, lines 29-31 briefly describes GORE-TEX Vascular Grafts which are ePTFE tubes having an exterior layer of ePTFE helically-applied tape. These commercially available vascular grafts (over 3.5 million implanted to date) represent the physical embodiment of the combination of Lee and Eilentropp except that they do not include the stent components of Lee. The purpose of the helical wrapping on these grafts is specifically to prevent circumferential dilitation during use as a vascular graft, i.e., the wrap prevents dilitation of the graft over time due to creep deformation under load, a well documented property of plastic structures. The present invention provides a method of making a helically-reinforced ePTFE tube which is distensible up to a second circumference (imposed by the wrapping). There is no suggestion in the combination of Lee and Eilentropp as to how a distensible, helically-wrapped graft might be achieved; simply adding the wrap of Eilentropp to the graft component of Lee would result in a dilitation-resistant graft analogous to the commercial GORE-TEX Vascular Graft. The specification at Figure 4, page 11, lines 10-16 and page 11, line 33 to page 13, line 8 describes how the inventive porous polymeric tube of the present invention is made and how it differs from the commercial GORE-TEX Vascular Graft. The prior use of helical wrapping clearly teaches away from distensibility; the present distensible graft incorporating a helical wrap is thus clearly non-obvious over the cited references.

VII. REJECTION OF CLAIMS 17 AND 18 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER LEE ('917) IN VIEW OF EILENTROPP ('966) AS APPLIED TO CLAIM 14 ABOVE, AND FURTHER IN VIEW OF SUMMERS, US 5,607,445.

Lee and Eilentropp are described above; Eilentropp simply adds the use of a helical wrap to construct a tubular form. As noted by the Examiner, Summers teaches that a stent may be either straight (with two ends) or branched (with three ends). He further concludes that it would have been obvious to have formed the modified Lee stent/graft in a branched form, and that the branched form might also include tapers.

Applicants acknowledge the prior existence of both tapered and branched grafts. The cited combination of references including Summers does not, however, teach or suggest in any way how the porous polymeric tube of the present invention might be provided with in a circumferentially distensible form resistant to recoil or with a limiting second circumference, regardless of whether embodied in straight, branched or tapered form. Thus, for the reasons already described above, these claims (as amended) are not obvious over the cited references.

VIII. REJECTION OF CLAIMS 31 AND 32 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER LEE ('917) IN VIEW OF SUMMERS ('445).

This rejection is analogous to the previous rejection described in Paragraph VII above, except that it does not include the helical wrap of Eilentropp. The presence or lack of the helical wrap does not effect the reasons for patentability of these claims; the amended claims are not obvious over this combination for the same reasons described in Paragraph VII above.

IX. REJECTION OF CLAIMS 20, 50, 56, 62 AND 68 UNDER 35 USC 103(A) AS BEING UNPATENTABLE OVER LEE ('917) ALONE OR LEE IN VIEW OF EILENTROPP ('966).

The references are described above. The claims in question pertain to the securing of the tube to blood vessels by the use of sutures. Applicants acknowledge the substantial prior use of sutures for securing grafts to blood vessels; however, in the claimed combination there is no suggestion to suture grafts of the type described by claim 1 (amended). Consequently these dependent claims are also non-obvious and patentable.

CONCLUSION

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,

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